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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,804	06/30/2003	Nobuko Yamamoto	03500.015716.1	2559

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EXAMINER	
BAUSCH, SARAE L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,804	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Sarae Bausch	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64, 66-73* is/are pending in the application.

4a) Of the above claim(s) *10,14-17,19,22,29 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-13,18,20,21,23-28,30-50,52-64 and 66-73* is/are rejected.

7)☒ Claim(s) *64* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to papers filed on 02/06/2006.

2. The claims submitted 06/03/2003 contain two claims numbered as 64 and no claim numbered as 65. In this office action, the second claim 64 has been renumbered to claim 65 and will be referred to as claim 65. Applicant is required to correct the numbering of the claims in response to this office action (see claim objections in this action).

Election/Restrictions

3. Applicant's election of species I (reactivity of nucleic – nucleic acid interactions) in the reply filed on 02/06/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 10, 14-17, 19, 22, 29, 51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/06/2006.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/942662, filed on 12/20/2001. This application claims priority to US application 09/942662 and foreign priority to JP 263395-2000 and 263505/2000.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

This application claims benefit to JP 263395-2000 and 263505/2000, filed on 8/31/2000, in a language other than English. An English translation of the non-English language provisional application and a statement that the translation is accurate must be filed in provisional application No. 10/608804. See 37 CFR 1.78(a)(5). The translation and statement that the translation is accurate required by 37 CFR 1.78(a)(5) is missing. Accordingly, applicant must supply the missing translation and statement that the translation is accurate in the present application. If the missing translation and statement that the translation is accurate are not filed (or the benefit claim withdrawn by the filing of an amendment or Supplemental Application Data Sheet) prior to the expiration of the time period set in this Office action, the present application will be abandoned. See 37 CFR 1.78(a)(5)(iv).

Drawings

7. The drawings are acceptable.

Sequence Rules

8. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. There are no sequence identifiers for the sequences listed throughout the specification. Applicant is required to thoroughly review the specification and comply with all sequence rules. For example, the following sequences in the specification do not have sequence identifiers: page 69 line 26, page 70 line 4, page 79 line 25, page 85 line 3-5, and figure 7. For any response to this office action to fully responsive, applicants are required to comply with sequence rules.

Claim Objections

9. Claim 52 is objected to because of the following informalities: the claim recites "lest" which is misspelled. Appropriate correction is required.

10. Claim 64 is objected to because of the following informalities: two claims are numbered claim 64 however there is no claim 65. The second claim 64 is being addressed in this action as claim 65, however applicant is required to correct the number of the two claims.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-9, 11-12, 18, 20-21, 23-25, 26, 34-38, 43-57, 63-64, 66-67, and 72-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (US Patent 5807522 Sep. 1998).

With regard to claim 1 and 45, Brown et al. teach a method of detecting differential expression of each of a plurality of genes in a first cell type with respect to expression of the same genes in a second cell type (see column 4, lines 52-59) (preparing two liquid test samples containing a component having a capability of binding oligonucleotide). Brown et al. teach mixtures of labeled cDNA from the two cell types is added to an array of polynucleotides

representing a plurality of known genes (preparing at least one oligonucleotide of which base sequence is known and binding oligonucleotide as probe to predetermined region on solid support to produce a detection substrate, claim 45) (preparing substrate with a first sample bound in a defined region and arranging plurality of second sample within region independently of one another, claim 1) (see column 4, lines 60-63). Brown et al. teach the array is examined by fluorescence to determine the relative expression of known genes in the two cell types by each spot (testing reactivity of first and second sample, claim 1) (detecting a complex and determining whether component is contained in each liquid test sample, claim 45) (see column 4, lines 64-67 and column 5, lines 1-5).

With regard to claim 2-6, 9, 11-12, 18, 20-21, 46-47, 49-50, 52, 54, 56, Brown et al. polynucleotides of about 50 bp (claim 46, 50) are on the array surface (1st sample) and a small volume of labeled DNA probe mixture (2nd sample) in a standard hybridization solution is loaded onto each cell and incubation at appropriate temperatures for hybridization (reactivity) (claim 2-3, 26) followed by reaction with detection reagents and analyzed using calorimetric, radioactive, or fluorescent detection (see column 13, lines 10-46). Brown et al. teach 100 DNA fragments representing all known mutations of a given gene fabricated on an array. Brown et al. teach the region of interest from each of the DNA samples from 96 patients could be amplified, labeled, and hybridized to the array. Brown et al. teach the solid support contains all 96 microarrays assayed with 96 patient samples are incubated, rinsed, detected, and analyzed using standard calorimetric, radioactive, or fluorescent detection and teaches the process can be reversed where the patient or organism's DNA is immobilized as the array elements and each array is hybridized

with a different mutated allele or genetic marker (claims 4-6, 9, 11-12, 18, 20-21, 46-47, 52, 54, 56) (see column 15, lines 18-51).

With regard to claim 7-8, 48-49, and 53, Brown et al. teach an array of cDNA clones representing genes hybridized with total cDNA from an organism to monitor gene expression (see column 15, lines 5-18). Brown et al. teach isolating mRNA from wild type Arabidopsis and reverse transcribing to obtain total cDNA using fluorescein nucleotide analog to label the cDNA product (see example 2, column 17, lines 43-67 and column 18, lines 1-31).

With regard to claim 23, 38, 55, and 67, Brown et al. teach an array of regions having a density of at least about 100/cm^2 (see column 6, lines 33-35).

With regard to claim 24, 34-37, 63-64, 66, Brown et al. teach a n array of regions on a solid support, a two dimensional array with discrete regions having a finite area (see column 6, lines 29-32). Brown et al. teach the regions in a microarray have typical dimensions between 10-250 μm and are separated from other regions in the array by about the same distance. Brown et al. teach the surface can be hydrophilic or hydrophobic character (claim 35, 64) (see column 7, lines 40-52). Brown et al. teach the array is formed in a plurality of analyte-specific reagent regions, each region may include a different analyte-specific reagent (claim 34, 64, 66). Brown et al. teach the spacing between each region and its closest neighbor is measured from center to center and between 20-400 μm (claim 36-37) (see column 9, lines 30-45).

With regard to claim 25, 57, Brown et al. teach the support is glass (see column 7, line 38-39).

With regard to claim 26, Brown et al. teaches an array of electrostatically bound polynucleotides (see column 4, lines 39-42).

With regard to claim 43-44 and 72-73, Brown et al. teaches a dispensing device to deposit a selected volume of solution on the surface (see column 3, lines 23-67 and column 4, lines 1-11).

13. Claims 1-9, 11-13, 18, 25, 27-28, 45-50, 52-53, and 57-59, are rejected under 35 U.S.C. 102(b) as being anticipated by Keller (US Patent 5656462 August 1997).

With regard to claim 1-3 and 45, 47, Keller et al. teach a method of producing sense mRNA on a solid support by binding polynucleotides with at least one sequence complementary to the polyadenylic acid tail of mRNA, at least one promoter, and one restriction enzyme recognition site to an insoluble support creating a nucleotide immobilized support (first sample bound to defined region), adding a sample solution containing mRNA with polyadenylatic acid tail to the support (second sample) and permitting the polyadenylic acid tail of the mRNA to hybridize with the complementary sequence (testing reactivity of the first and second sample) (claim 2-3) (see column 5, lines 5-50). Keller et al. also teaches adding a sample solution containing mRNA to a nucleotide-immobilized support and creating a first liquid phase (first sample), removing the first liquid phase and adding a reaction mixture of reverse transcriptase, dNTPS, to the solid phase incubating the reaction mixture and solid phase) and adding a second reaction mixture of DNA polymerase, DNA ligase, dNTPs to the solid phase (second sample) (testing reactivity of first and second sample) (see column 5, lines 50-67).

With regard to claim 4-9, 46, 50, 52, Keller et al. teach the immobilized oligonucleotides include nucleotide sequences complementary to mRNA and it is preferable that the length of such nucleotides be between 15 and 80 and preferably between 30 and 100 bases (see column 9, lines 5-10). Keller et al. teach the polynucleotides can be readily synthesized using techniques

known in the art, including using a DNA synthesizer (see column 9, lines 11-21). Keller et al. teaches that cell lysates can be placed into wells without further purification and the present invention can quickly synthesize cDNA and mRNA (see column 8, lines 27-44). Keller et al. teach a sample containing mRNA is applied to the insoluble support (see column 10, lines 53-65) (second sample).

With regard to claim 11-13, 18, 48-49, 53, Keller et al. teach synthesis of ds-cDNA, sense ss-cDNA, and PCR amplification of jun oncogene-specific ds-DNA from human leukocytes (see example 2, column 17, lines 65-67 and column 18 lines 1-67).

With regard to claim 25, 27-28, and 57-59, Keller et al. teach an insoluble support can be a glass microtiter plate (see column 8, lines 7-10). Keller et al. teach immobilizing polynucleotides to insoluble solid supports by covalent binding using functional groups such as carboxyl and amine residues (see column 9, lines 45-62). Keller et al. teach covalently attaching the 5' end of the polynucleotide to the insoluble support using maleimide groups (see column 9, lines 64-67 and column 10, lines 1-5).

14. Claims 1-2, 25-28, and 31-33, are rejected under 35 U.S.C. 102(b) as being anticipated by Chrisey (US Patent 5688642 November 1997).

With regard to claim 1-2, Chrisey et al. teach a solid support having exposed hydroxyl groups to form an organosilane monolayer and heterobifunctional crosslinkers (preparing substrate with a first sample) (see column 4, lines 20-25). Chrisey et al. teach binding a modified or unmodified nucleic acid molecule directly or indirectly to the organosilane either by electrostatic interactions (directly) or covalent attachment by heterobifunctional crosslinkers

(arranging plurality of second sample and testing the reactivity of the first and second sample) (see column 4, lines 33-48).

With regard to claim 25-28, 31-33, 57-59 and 61-62, Chrisey et al. teach the substrate may be glass (see column 7, lines 24-26). Chrisey et al. teach the silane contain terminal functional groups such as epoxy and thiol reactive linkers (see column 7, lines 37-43). Chrisey et al. teach a heterofunctional crosslinker useful for the covalent attachment of thiol modified synthetic DNA to an aminosilane-modified substrate was succinimidyl (maleimidophenyl)butyrate (see column 8, lines 8-13). Chrisey et al. teach the active agent attached to the modified surface can be natural or synthetic oligomers of DNA or RNA modified with a thiol or amino group (see column 8, lines 39-46).

15. Claims 1-3, 20, 24-25, 27-28, 30-42, 45-47, 50, 52, 54, 56-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Okamoto et al. (US Patent 6476215 Nov 2002)

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With regard to claim 1-3, 20, 24, 45, 47, 52, 54, and 56, Okamoto et al. teach a preparing a substrate containing three different probes (claim 20) by bubble jet printing followed by hybridization of ssDNA complementary to the probe and detection by fluorescence microscopy (see column 2 lines 36-60, and example 8, column 24, lines 15 through column 26 line 26).

With regard to claim 25, 27-28, 30-31, and 57-61, Okamoto et al. teach introducing a maleimide group onto a glass substrate by an amino group and reagent maleimidocaproyloxy succinimide (see column 6, lines 29-40). Okamoto et al. teach maleimido groups to the surface of the glass plate are introduced by reaction with the amino group and succinimidyl-4-(maleimidophyenyl)butyrate (see 12, lines 65-67).

With regard to claim 32-33 and 62, Okamoto et al. teach immobilization of nucleic acid by combination of epoxy group and amino group on a solid support (see column 6, lines 59-65).

With regard to claim 34-38, 63-67 Okamoto et al. teach a substrate with partitioned wall members to define a matrix with samples having different properties (see column 14, lines 1-7). Okamoto et al. teach the thickness of the matrix is determined by the matrix pattern, volume of wells, and volume of probe solution and preferably is 1-20 μm and teach a well density (spots) of 200 μm (see column 14, lines 11-20). Okamoto et al. teach a density of greater than 400/cm^2 (see column 14, lines 51-64).

With regard to claims 39-42, 46, 50, and 68-71, Okamoto et al. teach application of samples by ink-jet method. Okamoto et al. teach using a bubble jet method (see column 15, lines 29-31). Okamoto et al. teach application of 1 μM ssDNA with a base sequence complementary to DNA of SEQ ID No. 1 (18 base pairs) (second sample) nucleic acids for hybridization reaction. Okamoto et al. teach each spot had a diameter of 70-100 μm (see column 17, lines 35-65).

Claim Rejections - 35 USC § 112- Second Paragraph

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claim 32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

18. Claim 32 recites the limitation "method according to claim 28 wherein said chemical reaction is a reaction between an epoxy group introduced to the glass surface of the substrate and an amino group possessed by said first sample". There is insufficient antecedent basis for this limitation in the claim. Claim 28 requires a first sample to be bound to a substrate through a chemical reaction of maleimide groups introduced to a glass surface of the substrate with thiol groups possessed by said first sample. Claim 28 does not recite an amino group on the first sample or an epoxy group on the glass surface. It is unclear if applicant is intending to claim multiple different functional groups on the glass surface or if applicant is intending to claim that the thiol group, maleimide group, epoxy group and amino group interact together however it is unclear how this reaction will occur and what product would result from this reaction.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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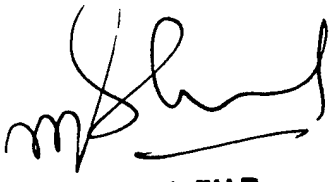

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